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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,671	FOERSTER ET AL.	
	Examiner	Art Unit	
	JEFFREY G. HOEKSTRA	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-52* is/are pending in the application.

4a) Of the above claim(s) *51 and 52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/13/2009 has been entered.

Notice of Amendment

2. In response to the amendment filed on 11/13/2009, amended claim(s) 49 and new claim(s) 50-52 is/are acknowledged. The current rejections of the claim(s) 49 is/are *withdrawn*. The following new and/or reiterated ground(s) of rejection is/are set forth:

Claim Objections

3. Claim 49 is objected to because of the following informalities: the positive recitation of "a plurality of small radiodense markers deployed as a biopsy marker material disposed within the inner lumen" in lines 5-6 should apparently read "a plurality of small radiodense markers deployed as the biopsy marker material and disposed within the inner lumen", "a plurality of small radiodense markers disposed within the

inner lumen and deployed as the biopsy marker material", or the like. Appropriate correction is required.

Election/Restrictions

4. Newly submitted claims 51 and 52 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 51 and 52 positively recite wherein the plurality of small radiodense markers are "permanent markers" or "bioabsorbable". These features appear to correspond to the permanently implanted, outward-energy anchoring markers of Figures 1-16 (Specification, page 15 lines 7-14 and page 22 lines 7-19) and the woven biodegradable polymer marker of Figure 20 (Specification, page 23 lines 2-6), respectively. These species of biopsy marker materials are substantially dissimilar and structurally divergent means for marking biopsy sites as opposed to the species elected by original presentation, the embodiment drawn to the plurality of small beads or pellets of radiodense calcium carbonate as best seen in Figure 19 (Specification, page 22 line 22 - page 23 line 1). Conversely, the Examiner notes that in the written description of the species elected by original presentation there appears to be no mention of the temporal duration the plurality of small beads or pellets of radiodense calcium carbonate reside in the biopsy site nor a mention of the physiological absorption and/or degradation thereof.

5. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 51 and 52 are withdrawn from

consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 49-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Burton (US 3,741,198).

9. For claim 49, Burton discloses a delivery system (as best seen in Figures 1, 2, 3, and 6) for delivering biopsy marker material (ferro-fluidic marking material 28) to a biopsy site (spinal column site 10) within a patient (patient 12) (Abstract, column 3 line 63 – column 6 line 57) (as best seen in Figures 1, 3, and 6), comprising *inter alia*:

- an elongate member (puncture needle 14) (column 4 line 66 – column 5 line 17 and column 6 lines 50-57) having a distal end (the insertion/inserted end of puncture needle 14 as best seen in Figures 1, 3, and 6), a discharge port in the distal end (the

open distal end of puncture needle 14 as best seen in Figures 3 and 6) and an inner lumen (the inner lumen of puncture needle 14 as best seen in Figures 3 and 6) extending therein to and in fluid communication with the discharge port in the distal end (as best seen in Figures 3 and 6);

- a plurality of small radiodense markers (ferro-fluidic marking material 28 comprised in part of a plurality of small ferromagnetic particles) (as best seen in Figures 3 and 6) (column 3 line 63 – column 4 line 17 and column 5 lines 8-17) disposed within the inner lumen of the elongate member (as best seen in Figures 3 and 6) (column 3 line 63 – column 4 line 17 and column 5 lines 8-17) and configured to be deployed as the biopsy marker material (the radiological diagnostic marking material 28 is deployed to diagnose abnormalities including tumors, column 1 lines 8-15) (as best seen in Figures 3 and 6) (column 3 line 63 – column 4 line 17 and column 5 lines 8-17); and
- an ejector (the syringe positively recited in column 5 lines 12-15) which is advancable with and coupled to said elongate member (column 5 lines 12-15) and which is configured to eject the biopsy marker material from the discharge port in said distal end of said elongate member (the injection of the marker material through the puncture needle via use of the syringe as positively recited in column 5 lines 12-15) to mark a desired biopsy site for locating the biopsy site during a future examination (in one example, Burton discloses that the spinal column, e.g. the desired biopsy site, is first marked with the ferro-fluidic marking material and then the material is located in the biopsy site during subsequent X-ray examination and/or fluoroscopic examination, column 5 lines 18-29).

10. For claim 50, Burton discloses the system, wherein the plurality of small radiodense markers are beads or pellets (28) (as best seen in Figures 3 and 6) (column 3 line 63 – column 4 line 17 and column 5 lines 8-17).

Response to Arguments

11. Applicant's arguments filed 11/13/2009 have been fully considered but they are not persuasive. Applicant argues the anticipatory rejection of claim 49 under 35 U.S.C. 102(b) as being anticipated by Burton.

12. Specifically applicant argues, Burton does not disclose, teach, and/or fairly suggest the following:

a) "*a plurality of small radiodense markers deployed as a biopsy marker material disposed within the inner lumen*. This structural limitation is not disclosed by Burton. Burton can't possibly disclose biopsy marker material as no biopsy is taking place in Burton. Still further, the ferrofluid of Burton does not mark a desired biopsy site for locating the biopsy site during a future examination. Thus, and as previously stated in the response to the last Office Action, the ferrofluid of Burton is not a marker material as contemplated, disclosed and claimed by Applicant."; and

b) "the ferrofluid of Burton is not used to mark a desired site for locating the biopsy site during a future examination and thus does not function as a marker as claimed."

13. The Examiner disagrees, maintains the rejection as set forth and cited above, and in response notes the following:

14. In response to applicant's argument (a) that Burton fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "a biopsy takes place") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

15. In response to Applicant's argument (a), the Examiner notes the claims and limitations therein are being treated on the merits with the broadest reasonable interpretation thereof consistent with the instant Specification.

16. The term "biopsy site" may be reasonably interpreted with its plain meaning to include "a position, location, or setting for the diagnostic study of tissue of a living body". Burton clearly discloses the deployment and injection of the radiographic ferrofluid for radiological diagnosis of abnormalities, including for example tumors. The "desired biopsy site" is the spinal column site where the marking fluid is injected. For example, when a tumor is found this may be considered a "biopsy site" as broadly as claimed.

17. Similarly, the term "biopsy marker material" may be reasonably interpreted with its plain meaning to include "a substance of which a thing is composed that is used as an indication for the diagnostic study of tissue of a living body". Burton clearly discloses the deployment and injection of the radiographic ferrofluid for radiological diagnosis of abnormalities, including for example biopsy-able tumors.

18. Although Burton discloses removing the ferrofluid material upon completion of the procedure, the biopsy site is first injected with the fluid to mark it and during "future" examination (i.e. during the subsequent X-ray portion of the procedure) the biopsy site

is located due to the radiodense marking characteristics of the ferrofluid and biopsy site diagnosed. The term "future" may be plainly defined as "time that is to be or come hereafter".

19. Furthermore, the Examiner notes the scope of the claimed invention does not include for example at least "obtaining a biopsy specimen" or "marking the location or margins of a lesion prior to removing the sample" (as disclosed in the instant Specification at at least page 6 lines 9-17); conversely, the scope of the claims merely recites a structure for *inter alia* ejecting with an ejector at a "biopsy site" small radiodense markers through a discharge port from a lumen of an elongate member for marking a site for locating it in the future.

Conclusion

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey G Hoekstra/
Examiner, Art Unit 3736